

# Guidance for Industry

## Guide to Minimize Microbial Food Safety Hazards of Melons

### ***DRAFT GUIDANCE***

**This guidance document is being distributed for comment purposes only.**

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 301-436-1700.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition**

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## **Table of Contents**

<b>I.</b>	<b>Introduction</b>
<b>II.</b>	<b>Background</b>
<b>III.</b>	<b>Scope and Use</b>
<b>IV.</b>	<b>Definitions</b>
<b>V.</b>	<b>Production and Harvest</b>
<b>VI.</b>	<b>Postharvest</b>
<b>VII.</b>	<b>Fresh-cut/Value-Added Processing</b>
<b>VIII.</b>	<b>Distribution</b>
<b>IX.</b>	<b>User Handling (Retail and Foodservice)</b>
<b>X.</b>	<b>References</b>

# **Guidance for Industry<sup>1</sup>**

## **Guide to Minimize Microbial Food Safety Hazards of Melons**

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

### **I. Introduction**

This guidance is intended to assist domestic firms and foreign firms exporting melons to the United States (U.S.) by recommending practices to minimize the microbial food safety hazards of their products throughout the entire melon supply chain. It identifies some, but not all, of the preventive measures that these firms may take to minimize these food safety hazards. This guidance document is not intended to serve as an action plan for any specific operation, but should be viewed as a starting point. We encourage each firm from the farm level through the retail or foodservice level to assess the recommendations in this guidance and then tailor its food safety practices to its particular operations by developing its own food safety programs based on the assessment of the potential hazards and its operations.

In addition, effective management of food safety requires that responsibility be clearly established among the many parties involved in the production of fresh produce. There may be many different permutations of ownership and business arrangements during the growing, harvesting packing, processing and distribution of fresh and fresh-cut melons. For this reason, it is important to identify which responsibilities rest with which parties, and to ensure that these responsibilities are clearly defined. For example, growers commonly contract with third parties to harvest their crops. It also is important that growers clearly identify which party is responsible for each applicable provision of this guidance, such as providing adequate toilet and handwashing facilities and worker training. Approaches to addressing responsibilities include delegating them to individuals within the firm and formally addressing them in contractual agreements when third parties are involved. Each party should be aware of its responsibilities to ensure that microbial food safety hazards for melons are minimized at each stage of the supply chain.

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<sup>1</sup> This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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This draft guidance is based primarily on industry guidelines for melons issued on November 7, 2005, “[Commodity Specific Food Safety Guidelines for the Melon Supply Chain.](#)” [Ref. 1] FDA conducted its own review of the provisions of the industry guidelines and made decisions to incorporate, modify, or exclude specific aspects of those guidelines based on the agency’s experience and information from other recent public and private programs.

This guidance is intended to supplement existing guidances, including the “[Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables](#)” (October 1998) ([GAPs Guide](#)), which applies to fresh produce commodities, and the “[Guidance for Industry: Guide to Minimize Food Safety Hazards for Fresh-cut Fruits and Vegetables](#)” (February 2008) ([Fresh-cut Guide](#)), which applies to fresh-cut produce. The GAPs Guide provides recommendations for growers, packers, and shippers to use good agricultural practices in those areas over which they have control to prevent or minimize microbial food safety hazards in fresh produce. The Fresh-cut Guide provides recommendations to fresh-cut produce processing firms to enhance the safety of fresh-cut produce by minimizing the microbial food safety hazards relative to fresh-cut processing operations. The information included in this melon-specific guidance is consistent with recommendations provided in the GAPs Guide and the Fresh-cut Guide.

This guidance also specifically refers to FDA's regulations in 21 CFR part 1, subpart J on the establishment, maintenance, and availability of records and 21 CFR part 110 on current good manufacturing practices in manufacturing, packing, or holding human food. The recommendations in this guidance complement, but do not supersede, the requirements in those regulations and any associated recommendations. Further, the recommendations in this guidance do not affect the applicability of any other Federal and State requirements and your responsibility to comply with them.

FDA will continue to evaluate how best to measure the extent to which the recommendations in this and other federal guidance documents, as well as industry standards and practices, are effective in reducing microbial contamination in melons. In particular, we are considering the extent to which more specific measures, such as metrics, should be utilized to help verify the implementation and efficacy of the Federal recommendations and industry practices.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

## **II. Background**

From 1996 to 2008, eighty-two foodborne illness outbreaks were associated with the consumption of fresh produce. Of these produce-related outbreaks, 13 (15.9%) were linked to melons. During this time period, melon-associated outbreaks accounted for 507 illnesses and 2

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deaths. All of the melon-associated outbreaks were due to bacterial agents. Cantaloupe was involved in 10 of the 13 outbreaks associated with melon consumption [Ref. 2].

In 1998, to improve the safety of fresh produce, FDA issued its GAPs Guide. The GAPs Guide provides general food safety guidance on the production and packing of fresh produce for critical production steps where food safety might be compromised during the growing, harvesting, transportation, cooling, packing and storage of fresh produce. More specifically, the GAPs Guide alerted fruit and vegetable growers, shippers, packers and processors to the potential microbiological hazards associated with various aspects of the production chain including: land history, adjacent land use, water quality, worker health and hygiene, pesticide and fertilizer use, equipment cleaning and sanitation and product transportation. Since its issuance, the GAPs Guide has been accepted widely.

### **III. Scope and Use**

This guidance covers melons that are grown and harvested for fresh market (i.e. fresh, unprocessed form) or for “fresh-cut/value-added products” (i.e., minimally processed, such as trimmed, peeled sliced or diced and then bagged or pre-packaged), cooled, shipped to retail, wholesale or processing, and offered for sale to the consumer. The use of the term “melons” in this document refers to cantaloupe (also known as muskmelons), honeydew, watermelon, and variety melons (e.g., “Canary,” “Crenshaw,” and “Galia”), both as raw agricultural commodities and the value-added fresh-cut products derived from them.

This guidance addresses microbiological hazards that may be associated with melons and appropriate control measures for such hazards. It does not specifically address chemical hazards. Consistent with the GAPs Guide and Fresh-cut Guide, this guidance also emphasizes the importance of employing prevention rather than elimination strategies to address microbiological hazards. Once fresh produce has been contaminated, removing, or killing the microbial pathogens while maintaining the fresh attribute of the produce, is very difficult. Prevention of microbial contamination at all steps in the field-to-fork continuum is preferable to treatment to eliminate contamination after it has occurred.

Although this guidance to industry does not specifically include a section for consumers, it is critical that consumers also handle fresh produce safely and not contaminate it. Consumers may refer to [“Safe Handling of Raw Produce and Fresh-Squeezed Fruit and Vegetable Juices.”](#)

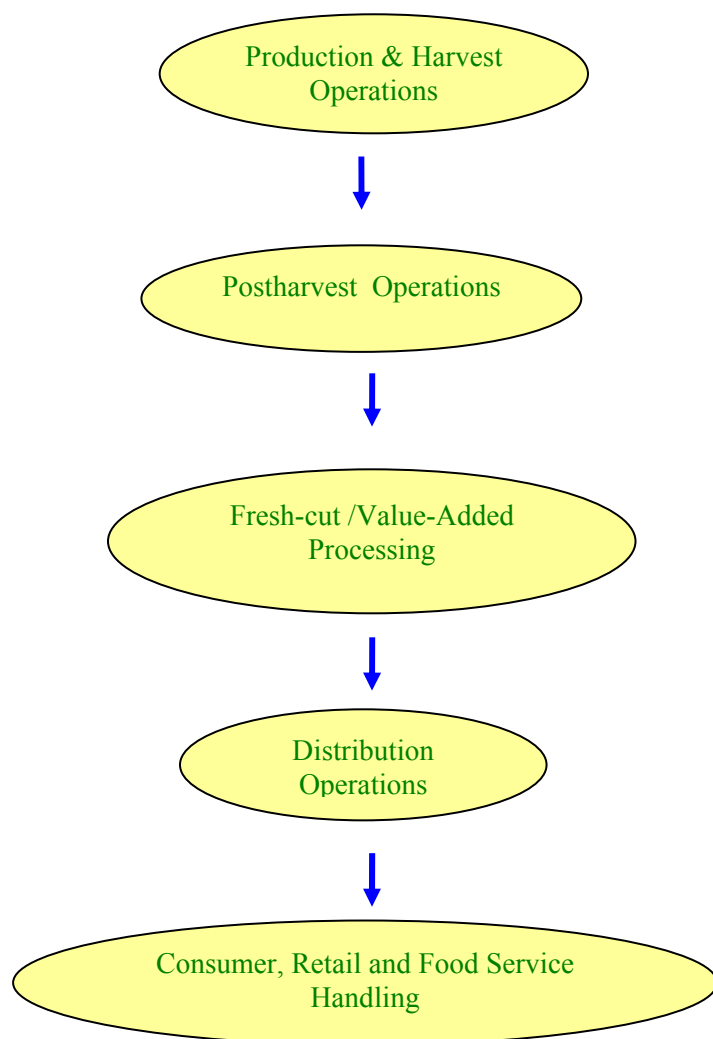
In the sections that follow, the melon “field-to-fork” continuum has been broken down into the following operations: production and harvesting, postharvest handling, fresh-cut/value-added processing, distribution and end user handling (retail and foodservice) (Figure 1). A diagram of the supply flow through these operations is provided in Figure 2. For each identified issue, general recommendations regarding the issue are made to raise awareness and allow individuals and firms involved in the melon field-to-fork continuum to consider actions that are appropriate to their operations. The identified issues in each section focus only on melons, as defined above,

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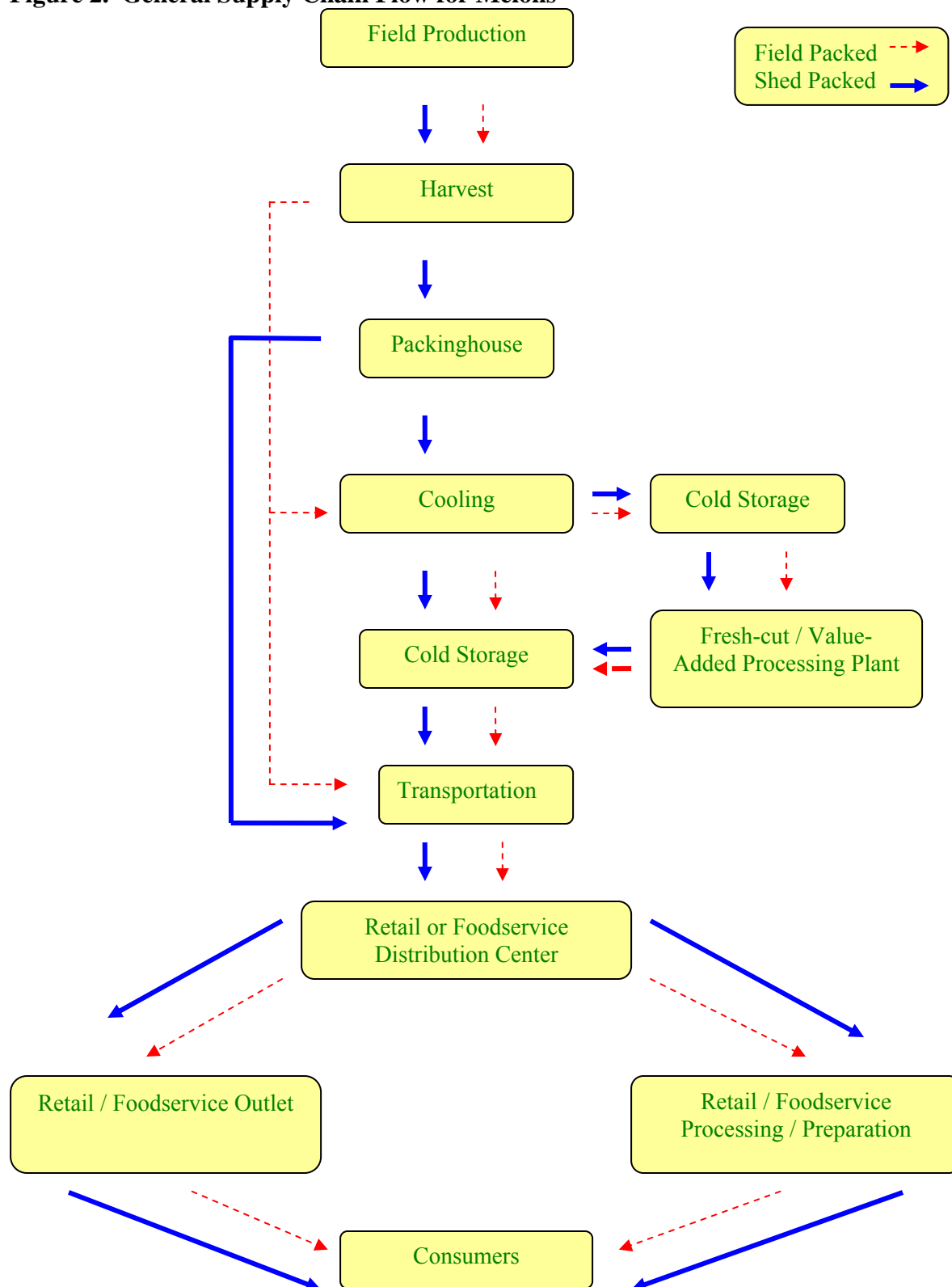
and may or may not apply to other specialty crops. Firms are encouraged to use this document to evaluate their operations and develop their own individual company food safety programs.

**Figure 1. Melon Unit Operations**



Note: Figure 1 is reprinted from the “Commodity Specific Food Safety Guidelines for the Melon Supply Chain” [Ref. 1]. Reprinted with permission.

**Figure 2. General Supply Chain Flow for Melons**



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Description: The diagram in Figure 2 depicts the general route melons take from field production to the consumers. Melons are either field-packed, as indicated by the dotted arrow, or shed-packed, as indicated by the solid arrow, and may go through the following process steps: harvest; packinghouse; cooling; cold storage; value-added processing plant; cold storage (again); transportation; retail or foodservice distribution center; retail/foodservice outlet; retail/foodservice/processing/ preparation; and consumers. Field-packed melons may go straight from harvest to cooling and transportation, as shown by the dotted arrows on the left side of the diagram, and shed-packed melons may go from packinghouse to transportation, as shown by the solid arrows on the left side of the diagram, before reaching the retail or foodservice distribution center, retail/foodservice outlet, retail/foodservice/processing/preparation, and consumers. Note: Figure 2 is reprinted from the “Commodity Specific Food Safety Guidelines for the Melon Supply Chain” [Ref. 1]. (Reprinted with permission).

## **IV. Definitions**

The following definitions apply to this guidance:

**Adequate** means that which is needed to accomplish the intended use in keeping with good practice.

**Clean** means that food or food-contact surfaces are washed and rinsed and are visually free of dust, dirt, food residues, and other debris.

**Control** means to manage the conditions of an operation in order to be consistent with established criteria, and to follow correct procedures.

**Control measure** is any action or activity that can be used to prevent, reduce, or eliminate a microbiological hazard.

**Cull** means to remove any product that shows signs of physical damage (such as skin breaks or decay).

**Current Good Manufacturing Practices (CGMPs)** refers to the CGMP regulations that are found in 21 CFR 110 (Current Good Manufacturing Practices in Manufacturing, Processing, Packing, or Holding Human Food).

**Environmental assessment** means an evaluation of the growing environment, taking into consideration factors including topography, hydrology, geographical features, climatic conditions, land history, near-by land use, agricultural water, and domestic animal and wildlife presence to evaluate any safety risks that may affect the potential for melons to be contaminated. Environmental assessments may be conducted prior to planting, during production, and immediately prior to harvest.



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**Facilities** are the buildings and other physical structures used for or in connection with the harvesting, washing, sorting, storage, packaging, labeling, holding, or transport of fresh produce.

**Food-contact surfaces** are those surfaces that contact fresh produce and those surfaces from which drainage onto the produce or onto surfaces that contact the produce may occur during the normal course of operations. “Food-contact surfaces” include equipment, such as containers and conveyor belts, which contact fresh produce, whether used in harvesting, post-harvesting, or packaging operations. “Food-contact surfaces” do not include items such as tractors, forklifts, hand trucks and pallets that are used for handling or storing large quantities of contained or packed fresh produce and that do not come into actual contact with the food.

**Fresh-cut fruits and vegetables or fresh-cut produce refer to** fresh fruits and vegetables for human consumption that have been minimally processed and altered in form by peeling, slicing, chopping, shredding, coring, or trimming, with or without washing, prior to being packaged for use by the consumer or a retail establishment (e.g., pre-cut, packaged, and ready-to-eat salad mixes). Fresh-cut produce does not require additional preparation, processing, or cooking before consumption, with the possible exception of washing or the addition of salad dressing, seasoning, or other accompaniments.

For different commodities, the fresh-cut form may vary. For example, the form of fresh-cut melons may be sliced and cubed, while the fresh-cut form of carrots may be peeled and cut into julienned sticks or baby carrots.

**GAPs Guide** refers to the guidelines set forth in the “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables,” which was issued by FDA in 1998.

**Hazard** means a biological, chemical, or physical agent that is reasonably likely to cause human illness or injury in the absence of its control.

**Human pathogen** means a microorganism capable of causing disease or injury to people. This is different from a plant pathogen which may cause disease to plants.

**Nontransporter** means a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation.

**Packinghouse or “packing shed”** means a facility where raw agricultural commodities are washed, trimmed, or sorted and packed in commercial containers, e.g., cartons or totes.

**Pest** means any animal or insect of public health importance including birds, rodents, cockroaches, flies, and larvae that may carry pathogens that can contaminate food.

**Raw agricultural commodity (RAC)** means any food in its raw or natural state, including all fruits and vegetables that are washed, colored, or otherwise treated in the unpeeled natural form prior to marketing.

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**Ready-to-eat (RTE)** describes foods that need no further preparation (e.g., washing or cutting) before eating.

**Risk** is a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

**Shed packed** refers to melons that are graded, sorted, sized, washed, cooled, packed, and placed on pallets in a packing shed/packinghouse.

## **V. Production and Harvest**

### **Climatic Production Conditions and Environment**

FDA recommends that growers give special consideration to environmental and production field practices specific to melon production. Melons that are chill sensitive are grown in warm weather conditions. Warm, humid conditions may favor human pathogen persistence and increase wildlife pest pressure and activity [Ref. 3]. Many wildlife species (e. g., birds, insects, amphibians, and snakes) that may be present in the production environment are known to be potential carriers of human pathogens [Ref. 4]. Heavy rains may increase melons' exposure to pathogens as soil contaminated with pathogens can splash onto melons.

FDA recommends:

- Conducting environmental assessments on the topography, land history, risk of flooding, adjacent land use, and domestic animal and wildlife presence associated with the production environment, using concepts that are outlined in the GAPs Guide (to the extent that any of these environmental factors are present).
- Monitoring and reducing, to the extent possible, domestic animal, wildlife, and insect activity in melon production environments that may contaminate water and soil with human pathogens and directly or indirectly contact melons, thereby increasing the risk of product contamination.
- Evaluating whether to harvest portions of melon fields when there is evidence of unusually heavy wildlife pest infestations (e.g., presence of wildlife feces, large areas of animal tracks, or burrowing).
- Training harvest employees to recognize and report signs and evidence of wildlife pest infestations (e.g., feces) and take appropriate action.
- Delaying harvest and performing extra washing when heavy rains have recently occurred. Heavy rains may increase the likelihood of soil-to-melon contamination.

### **Melon Rind Surface Characteristics**

Melons may have smooth or netted rind surfaces. Significantly more foodborne illness outbreaks have been associated with melons that have netted rinds [Ref. 6, 7]. Human pathogens may

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adhere to, survive on, and be more difficult to eliminate from, netted melon rind surfaces [Ref. 8-10].

FDA recommends:

- Carrying out practices that prevent or minimize surface contamination of melons, especially those with netted rinds, because once surface contamination occurs elimination of contamination is very difficult.

### **Stem Scar and Melon Maturity (Cantaloupes)**

Cantaloupe harvest is usually based on the melon stage of maturity as judged by the formation of an abscission zone between the vine and the melon. This characteristic of cantaloupe maturity is commonly called “slip,” and most melons are harvested between 3/4 and full slip. Cantaloupe stem scars may provide a potential route for entry of human pathogens to the edible flesh of melons [Ref. 9, 10]. As melons mature and ripen, they have a greater propensity to allow for the survival and multiplication of human pathogens on their surface [Ref. 11].

FDA recommends:

- Implementing postharvest handling practices to minimize stem scar and rind infiltration of human pathogens into the edible portions of melon flesh. (See Section VI, Postharvest Operations).

### **Direct Melon-to-Ground Contact**

Melons frequently directly contact soil during growth and development. Some growers place melons on cups (i.e., small plastic pads) or plastic-covered beds to prevent direct melon-to-soil contact and thereby reduce ground spot development. Melons also may be hand turned multiple times by field employees during the growing season to prevent ground spot development. Melon ground spots have been demonstrated to have significantly greater microbial populations than non-ground spot areas of melon rinds [Ref. 8].

FDA recommends:

- Evaluating soil amendments where melons directly contact soil.
- Evaluating the type of irrigation (such as furrow or drip) used to minimize soil wetting where melons directly contact soil.
- Evaluating employee hygiene practices (especially hand washing and glove use) where melons are turned by hand to reduce ground spot formation.
- Using clean sanitary materials where cups or plastic sheeting are used.

### **Mechanical Damage**

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Melons are heavy, making them susceptible to mechanical damage during harvest and postharvest handling operations.

FDA recommends:

- Using deceleration padding (when part of harvest and postharvest handling equipment) that is constructed of materials that can be cleaned and sanitized.
- Minimizing mechanical damage such as rind punctures, cracks, and bruising, as these wounds may provide entry points for pathogens.

### **Multiple Harvests**

Multiple melon harvests may increase the likelihood of melon contamination due to increased wildlife and insect pressures because of the presence in the field of melons mechanically damaged during prior harvest operations.

FDA recommends:

- Training harvest employees to recognize and not harvest melons that have mechanical damage or possible contamination from previous harvest operations.
- Evaluating ways to reduce flying insect access, to the extent possible, to animal feces and other likely sources of human pathogens that may contaminate non-harvested melons in the field.
- Evaluating ways to dispose of culled melons which reduce the potential for melon culls to serve as animal and insect pest attractants. This will reduce the potential for insect/pest-to-melon fruit contamination.

### **Documentation and Records**

As a general practice, it is important that firms that produce and harvest melons maintain documentation and records related to operational information about the product and practices, as well as tracing information about the product. It also is important to note that subject to certain exceptions, existing FDA regulations at 21 CFR part 1, subpart J, “Establishment, Maintenance, and Availability of Records,” already impose certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. These records must include identifying information regarding the food. The recommendations below complement, but do not supersede, existing recordkeeping requirements in part 1, subpart J. Note: Farms (as defined in the regulation) are excluded from the recordkeeping requirements of part 1, subpart J.

***Operational records*** about products and practices can be helpful to firms. First, such records help ensure consistency of production, packing, and processing operations and end-product quality and safety. They are more reliable than human memory and serve as a useful tool to

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identify areas where inconsistencies occur in operations and corrective actions or further employee training may be needed. Furthermore, maintaining adequate documentation and records could assist in identifying or ruling out factors potentially contributing to contamination if product implicated in an outbreak is traced to a particular farm or facility.

FDA recommends:

- Developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices, field, facility and vehicle cleaning and sanitation, and employee training programs.
- Maintaining records for significant activities performed, such as monitoring of water sources and use; testing water quality; treating water; monitoring for signs of animal intrusion; cleaning and sanitation of equipment, containers, and vehicles; employee training; and corrective actions taken.
- Recording information such as the date and time, name of person(s) who completed the record, the location of the field and location in the field, if applicable, and the activity being monitored in the documentation.

**Product tracing** refers to the ability to follow the movement of a food through specified stage(s) of production, packing, processing, and distribution. Tracing information about the product facilitates tracking the physical movement of a product from its original source through intermediate sources to its final recipient and tracking product from the final recipient back to its source. Effective product tracing systems can serve as an important complement to food safety programs intended to prevent microbial contamination.

FDA recommends:

- Utilizing information outlined in the GAPs Guide and the FDA [“Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations”](#) (issued on April 2001 and updated on June 2006) ([Guide to Traceback Investigations](#)) to develop a product tracing system applicable to the melon supply chain.
- Developing and maintaining standardized, clear records that can be used to enhance the ability to follow the movement of the product. Examples of such records include records with product identifying information (i.e., labels), invoices, inventory records, bills-of-lading, and shipping/receiving records.

## **VI. Postharvest**

### **Packinghouse and Field Packing Equipment Cleaning and Sanitation**

Field packing equipment and packinghouse facility sanitary design and sanitation programs are critical to ensuring that melons exiting these unit operations do not experience net increases in microbial populations [Ref. 5]. Field packing equipment and packinghouse operations may be

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used seasonally and thus be dormant for many months, leaving them susceptible to pest infestations.

FDA recommends:

- Appropriately protecting from pest infestations field packing equipment and packing house operations that may be dormant for many months.
- Using appropriate cleaning, sanitation, and pest removal and exclusion measures before operations commence.
- Using field packing and packinghouse equipment designed to facilitate cleaning and sanitation of melon contact surfaces (including padding) and constructed of materials that may be easily cleaned and sanitized.
- Validating and verifying packinghouse or field packing/harvest sanitation procedures to ensure that melons are not experiencing microbial contamination or build-up during this unit operation.
- Validating and verifying that melon wetting and brushing operations are not a potential source of melon contamination or cross-contamination.

### **Packinghouse Melon Dump Operations**

Melons typically are unloaded from field bins, open flat bed wagons, or gondolas by dry dump or water dump operations. Melons also may be floated out of gondolas by placing gondolas into water filled sumps that allow melons to be floated out of the gondolas. In this unit operation, there is the potential for melon-to-melon, food-contact surface-to-melon, and melon-to-water-to-melon cross-contamination [Ref. 5].

FDA recommends:

- Where dry dump stations are used, using melon food-contact surfaces (including padding materials) constructed of materials that can be cleaned and sanitized.
- Where dry dump stations are used, instructing employees not to walk or stand on dry food-contact surfaces during operations as this may increase the likelihood of food-contact surface contamination.
- Removing melons from harvest vehicles and containers by means other than immersion of the gondolas, trailers, or wagons to reduce potential product cross-contamination with field or road debris.
- Ensuring that water is of sufficient microbial quality for its intended use. Using dump tank water with sufficient water disinfectant present and monitoring the levels to reduce the potential risk of cross-contamination. Note: The primary purpose of the water disinfectant is not to clean the melons but rather to prevent the water from becoming contaminated should pathogens be introduced into the water from melons. The contaminated water could then act as a source of contamination for incoming melons.

### **Melon Cooling Medium**

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Melons typically are cooled by forced-air cooling or by use of a chilled water drench or flume immersion. Melon cooling with water, if done correctly, may reduce microbial loads on the outside surface of melons by 2-3 logs CFU [Ref. 12]. Microbial reduction on melon surfaces is dependent on disinfectant concentration and contact time. However, once present on the surface of a melon, human pathogens cannot be completely eliminated by washing [Ref. 8]. Prolonged soaking of melons in aqueous solutions containing wash water disinfectants is not an effective means of eliminating surface microbial contamination of the melon rind and may actually aid in the infiltration of human pathogens into the edible portions by creating an infiltration driving force. Melon cooling water also may be a significant source of microbial cross-contamination if there is insufficient water disinfectant present. In addition, because melon cooling water is colder than the melons, infiltration of small amounts of cooling water may enter melons through the stem scar and rind [Ref. 9]. Forced-air cooling operations can avoid the risk of infiltration but also may spread product contamination if forced-air cooling equipment is not cleaned and sanitized regularly.

FDA recommends:

- Evaluating water quality of cold water used to cool melons to ensure that water is of sufficient microbial quality for its intended purpose.
- Evaluating and monitoring water disinfectant levels to ensure that disinfectant is present at levels sufficient to reduce the potential risk of cross-contamination when melon cooling water is re-circulated. If melons are fully submerged in water as a means of cooling, they are more likely to have cooling water infiltrate into the melons and consideration should be given to cooling water quality variables such as pH, soil (including organic) load, turbidity, and product through-put capacity, to ensure that the wash water disinfectant of choice is effective in reducing the potential for water-to-melon cross-contamination (see [Ref. 11] for details).
- Using single pass (or one use) cooling water of sufficient quality for this intended purpose also may be used to cool product.
- Cleaning and sanitizing equipment on a regular basis to ensure that the potential for cross-contamination is minimized when forced-air cooling is used to cool melons.

### **Cooling Delays**

Delays in melon cooling when melon rinds are wet from washing operations or from dew may allow for multiplication of human pathogens on the rind surface of melons [Ref. 13].

FDA recommends:

- Implementing melon handling operations that minimize the incidence of melon surface moisture to reduce potential plant and human pathogen growth.
- Cooling and cold storing melons as soon as possible after harvest, if melons are to be air cooled.

### **Fungicide Treatment**



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Melons may be treated by aqueous spray or immersion with fungicides to extend their postharvest life. Some crop protection chemicals, including fungicides, are not bactericidal or virucidal and do not significantly change or reduce the survival or growth of some human pathogens [Ref. 14]. If the water used for postharvest fungicide application is contaminated with human pathogens, the melon rind surface may become contaminated with human pathogens.

FDA recommends:

- Evaluating water in water-based fungicide solutions used for postharvest melon treatments to ensure that the water is of sufficient microbial quality for its intended purpose.
- Evaluating and monitoring water temperature where hot water treatments are used as an alternative to postharvest chemical fungicide treatments to ensure that such water is maintained at an appropriate temperature, that water disinfectant is present at sufficient levels, and that the temperature/disinfectant levels are maintained at levels sufficient to reduce the potential risk of cross-contamination.

### **Flying Insect Control**

Melons have very high sugar content and are extremely attractive to flies and other insects that may cross-contaminate melons.

FDA recommends:

- Implementing an aggressive melon cull disposal and waste removal program to limit field, packinghouse, and cooler culls and thus reduce the potential for insect-to-melon contamination.
- Employing methods to reduce flying insect access to animal feces and other likely sources of human pathogens.

### **Top Icing of Melons**

Melons are typically top iced after cooling as a means of temperature control during transport and distribution. Ice will melt at refrigeration temperatures during transportation and distribution operations. Melting ice water flowing through boxes of melons may increase the risk of melon cross-contamination within and among pallets of melons.

FDA recommends:

- Employing alternative means of keeping melons cool because top icing is not particularly effective in cooling or keeping melons cold.
- Ensuring that the water used to make ice is of sufficient microbial quality for its intended use.
- Using ice that contains a water disinfectant at sufficient concentration to reduce the



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potential for cross-contamination.

- Transporting, storing, and using ice under sanitary conditions.
- Using plastic pallet shrouds to protect product from potential cross-contamination from pallets of melon placed in storage racks above other melon pallets, if ice is used.

### **Documentation and Records**

As a general practice, it is important that firms involved in postharvest operations maintain documentation and records related to operational information about the product and practices, as well as tracing information about the product. It also is important to note that subject to certain exceptions, existing FDA regulations at 21 CFR part 1, subpart J, “Establishment, Maintenance, and Availability of Records,” already impose certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. These records must include identifying information regarding the food. The regulation requires, among other things, that records maintained by nontransporters include an “adequate description” of the food, including brand name and specific variety, and provides an example of “romaine lettuce, not just lettuce.” The recommendations below complement, but do not supersede, existing recordkeeping requirements in part 1, subpart J.

***Operational records*** about products and practices can be helpful to firms. First, such records help ensure consistency of production, packing, and processing operations and end-product quality and safety. They are more reliable than human memory and serve as a useful tool to identify areas where inconsistencies occur in operations and corrective actions or further employee training may be needed. Furthermore, maintaining adequate documentation and records could assist in identifying or ruling out potential contributing factors of contamination if product implicated in an outbreak is traced to a particular farm or facility.

FDA recommends:

- Developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices, field, facility and vehicle cleaning and sanitation, and employee training programs.
- Maintaining records for significant activities performed, such as monitoring of water sources and use; testing water quality; treating water; monitoring for signs of animal intrusion; cleaning and sanitation of equipment, containers, and vehicles; employee training; and corrective actions taken.
- Recording information such as the date and time, name of person(s) who completed the record, and the activity being monitored in the documentation.

***Product tracing*** refers to the ability to follow the movement of a food through specified stage(s) of production, packing, processing, and distribution. Tracing information about the product facilitates tracking the physical movement of a product from its original source through intermediate sources to its final recipient and tracking product from the final recipient back to its

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source. Effective product tracing systems can serve as an important complement to food safety programs intended to prevent microbial contamination.

FDA recommends:

- Utilizing information outlined in the GAPs Guide and the FDA Guide to Traceback Investigations, to develop a product tracing system applicable to the melon supply chain.
- Developing and maintaining standardized, clear records that can be used to enhance the ability to follow the movement of the product. Examples of such records include records with product identifying information (i.e., labels), invoices, inventory records, bills-of-lading, and shipping/receiving records.

## **VII. Fresh-Cut/Value-Added Processing**

Fresh-cut processors are reminded that FDA's regulations in part 110 establish CGMPs for preparing, packing or holding food. The CGMP regulations include both binding requirements and non-binding recommendations relating to personnel, buildings and facilities, equipment, and production and process controls. Part 110 uses the word "shall" to state mandatory requirements and the word "should" to state recommended or advisory procedures. Fresh-cut fruits and vegetables, including melons, are considered "processed food" as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(gg)). Thus fresh-cut processors of melons are subject to the CGMP regulations. The practices provided in this guidance, including those applicable to fresh-cut processors, are recommendations that complement, but do not supersede, the requirements and recommendations in part 110.

### **Pre-Processing Treatments**

In recent years, there have been foodborne illness outbreaks and product recalls associated with melons due to contamination with *Salmonella*. Although not the only possible route of contamination, edible portions of the melon flesh may be contaminated in the cutting or rind removal process because microbial contamination on the outside rind of the melon may be spread by the knife blade [Ref. 15]. Due to their possible direct contact with soil, melon ground spots have been found to have higher microbial populations associated with them and are typically more susceptible to accelerated decay by plant pathogens than the rest of the melon. Decayed melon lesions caused by plant pathogens also may act as harborage for human pathogens [Ref. 9].

FDA recommends:

- Avoiding use of whole melons that have visible signs of decay or damaged rinds (e.g., mechanical damage or cracking) for fresh-cut melon production due to the increased risk of the presence of human pathogens in melons with decay or damage [Ref. 9]. When in doubt about the use of a decayed melon, throwing it out.

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- Thoroughly washing whole melons used for fresh-cut melon products before cutting or peeling.
- Using water of sufficient microbial quality for its intended purpose to wash melons before cutting or peeling.
- Using sufficient concentration/activity of a water disinfectant and monitoring the concentration/activity used for water that may be re-circulated, re-used or used in a single container to wash melons prior to cutting or peeling in order to reduce the potential for transfer of pathogens from the water to the melon.
- Washing melons before cutting or peeling, which, if done appropriately, may reduce microbial populations on the outside surface of melons by 2-3 logs CFU [Ref. 12]. Note: Microbial reduction on melon surfaces is dependent on disinfectant concentration and contact time. Also, once human pathogens are present on the surface of a melon, they cannot be completely eliminated by washing, and soaking melons in aqueous solutions containing wash water disinfectants for extended periods of time is not an effective means of eliminating surface microbial contamination of the melon rind; doing so may actually aid in the infiltration of human pathogens into the edible portions by creating an infiltration driving force.
- Using hot water, steam, or other treatments to surface disinfect the melon rind of whole melons used to produce fresh-cut melon products before peeling or cutting operations commence [Ref. 12]. Note: If surface heat treatments are used to surface disinfect whole melons, be aware that there may be an increased risk of *Clostridium botulinum* toxin formation in temperature abused, modified atmosphere packaged fresh-cut melons [Ref. 16].
- Cleaning and sanitizing cutting knife blades or peeling knife blades on a regular basis to reduce the potential for melon-to-knife blade-to-melon cross-contamination during the cutting or peeling process. Monitoring knife blade sanitizing solutions to ensure that the knife blade sanitizer is present at sufficient levels to achieve its intended purpose and does not promote the potential for cross-contamination.

### **Potential for Growth of Human Pathogens on Edible Melon Flesh**

Human pathogens may proliferate rapidly on fresh-cut melon products held under temperature abuse conditions [Ref. 17].

FDA recommends:

- Storing and distributing fresh-cut melon products at 32-41°F (0-5°C) because fresh-cut products, unlike whole melons, are not sensitive to chilling injury.

### **Documentation and Records**

As a general practice, it is important that firms involved in fresh-cut/value-added operations maintain documentation and records related to operational information about the product and practices, as well as tracing information about the product. It also is important to note that subject to certain exceptions, existing FDA regulations at 21 CFR part 1, subpart J,

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“Establishment, Maintenance, and Availability of Records,” already impose certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. These records must include identifying information regarding the food. The regulation requires, among other things, that records maintained by nontransporters include an “adequate description” of the food, including brand name and specific variety, and provides an example of “romaine lettuce, not just lettuce.” The recommendations below complement, but do not supersede, existing recordkeeping requirements in part 1, subpart J.

***Operational records*** about products and practices can be helpful to firms. First, such records help ensure consistency of production, packing, and processing operations and end-product quality and safety. They are more reliable than human memory and serve as a useful tool to identify areas where inconsistencies occur in operations and corrective actions or further employee training may be needed. Furthermore, maintaining adequate documentation and records could assist in identifying or ruling out potential contributing factors of contamination if product implicated in an outbreak is traced to a particular farm or facility.

FDA recommends:

- Developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices, sanitation, facility and vehicle cleaning and sanitation, and employee training programs.
- Maintaining records for significant activities performed, such as testing water quality and disinfectant level; monitoring storage temperatures; cleaning and sanitation of equipment, containers, and vehicles; employee training; and corrective actions taken.
- Recording information such as the date and time, name of person(s) who completed the record, and the activity being monitored in the documentation.

***Product tracing*** refers to the ability to follow the movement of a food through specified stage(s) of production, packing, processing, and distribution. Tracing information about the product facilitates tracking the physical movement of a product from its original source through intermediate sources to its final recipient and tracking product from the final recipient back to its source. Effective product tracing systems can serve as an important complement to food safety programs intended to prevent microbial contamination.

FDA recommends:

- Utilizing information outlined in the GAPs Guide and the FDA Guide to Traceback Investigations to develop a product tracing system applicable to the melon supply chain.
- Developing and maintaining standardized, clear records that can be used to enhance the ability to follow the movement of the product. Examples of such records include records with product identifying information (i.e., labels), invoices, inventory records, bills-of-lading, and shipping/receiving records.

## **VIII. Distribution**

Firms involved in distribution operations relating to melons are reminded that FDA's regulations in part 110 establish CGMPs for preparing, packing or holding food. The practices provided in this guidance, including those applicable to firms involved in distribution operations, are recommendations that complement, but do not supersede, the requirements and recommendations in part 110. Establishments engaged solely in the harvesting, storage, or distribution of one or more RACs, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public; however, generally are not subject to the requirements of part 110, as provided in 21 CFR 110.19.

### **Potential for Growth of Human Pathogens on Edible Melon Flesh**

Temperature and time controls for the safety of fresh-cut melons are important measures to prevent the potential rapid and prolific growth of human pathogens [Ref. 17].

FDA recommends:

- Holding fresh-cut melon products at 0° - 5°C (32° - 41°F) during storage and at point of service to prevent the potentially rapid and prolific growth of human pathogens, consistent with the [FDA 2005 Food Code](#) and any applicable state and local requirements.

### **Transportation Vehicles**

Melons and fresh-cut melon products can take many routes to the end user, including direct or indirect shipments through intermediate distributors and warehouses. It is important to manage each step of each route to reduce, control, or eliminate the risk of contamination.

FDA recommends:

- Transporting melons and fresh-cut melon products in clean, sanitary shipping containers or trailers.
- Implementing inspection and evaluation programs of shipping containers and trailers to verify that food safety needs are being met by the use of such containers. Evaluating items such as the condition of the container or trailer, including the overall cleanliness of the walls and floor, the structural condition (e.g., free from damage to walls, floor or ceiling, including exposed insulation and holes), the absence of off-odors or unusual smells; and the functioning of the chilled air delivery chute.
- Addressing sanitation during the transportation of melon products in contracts with transportation companies. For example, including restrictions on previous cargoes to avoid the possibility of cross-contamination.

### **Documentation and Records**

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As a general practice, it is important that firms involved in distribution operations of melons maintain documentation and records related to operational information about the product and practices, as well as tracing information about the product. It also is important to note that subject to certain exceptions, existing FDA regulations at 21 CFR part 1, subpart J, “Establishment, Maintenance, and Availability of Records,” already impose certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. These records must include identifying information regarding the food. See § 1.352 in FDA’s regulations for further information on the types of records transporters must maintain. The recommendations below complement, but do not supersede, existing recordkeeping requirements in part 1, subpart J.

***Operational records*** about products and practices can be helpful to firms. First, such records help ensure consistency of distribution operations. They are more reliable than human memory and serve as a useful tool to identify areas where inconsistencies occur in operations and corrective actions or further employee training may be needed. Furthermore, maintaining adequate documentation and records could assist in identifying or ruling out potential contributing factors of contamination if product implicated in an outbreak is traced to a particular farm or facility.

FDA recommends:

- Developing and maintaining written food safety plans and SOPs for areas such as vehicle cleaning and sanitation, and employee training programs.
- Maintaining records for significant activities performed, such as monitoring of storage temperatures; cleaning and sanitation of equipment, containers, and vehicles; employee training; and corrective actions taken.
- Recording information such as the date and time, name of person(s) who completed the record, and the activity being monitored in the documentation.

***Product tracing*** refers to the ability to follow the movement of a food through specified stage(s) of production, packing, processing, and distribution. Tracing information about the product facilitates tracking the physical movement of a product from its original source through intermediate sources to its final recipient and tracking product from the final recipient back to its source. Effective product tracing systems can serve as an important complement to food safety programs intended to prevent microbial contamination.

FDA recommends:

- Utilizing information outlined in the GAPs Guide and the FDA Guide to Traceback Investigations to develop a product tracing system applicable to the melon supply chain.
- Developing and maintaining standardized, clear records that can be used to enhance the ability to follow the movement of the product. Examples of such records include records

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*Draft — Not for Implementation*

with product identifying information (i.e., labels), invoices, inventory records, bills-of-lading, and shipping/receiving records.

### **IX. User Handling (Retail and Foodservice)**

As noted, in recent years, there have been foodborne illness outbreaks and product recalls associated with melons due to inadvertent contamination with *Salmonella*. Although not the only route of contamination, edible portions of the melon flesh may be contaminated in the cutting or rind removal process because microbial contamination on the outside rind of the melon may be spread by the knife blade involved in the cutting and/or peeling process.

Specific procedures for storing and displaying food, for excluding or restricting ill employees, for washing hands, date-marking, and for washing and sanitizing equipment can be found in the [FDA Food Code](#). The FDA Food Code is a model code developed by FDA to assist and promote consistent implementation of national food safety regulatory policy among the local, State, and tribal governmental agencies that have primary responsibility for the regulation or oversight of retail level food operations.

Further considerations for melons are found below. In addition, handlers of melons should be aware of and follow all Federal, State, and local requirements. Melons may be handled extensively at retail or in food service operations; therefore, it is of particular importance to wash hands thoroughly with soap and water before cutting or handling melons and to rewash hands as necessary.

FDA recommends:

- Avoiding use of whole melons that have visible signs of decay or damaged rinds (e.g., mechanical damage or cracking) due to the increased risk of the presence of human pathogens [Ref. 9]. When in doubt about the use of a decayed melon, throwing it out.
- Washing hands thoroughly with soap and water before cutting melons.
- Before cutting, washing the outer surface of the melon thoroughly under running cool tap water to remove surface dirt, scrubbing melons with a clean produce brush, and cutting away any bruised or damaged areas before serving. Note: For retail and foodservice establishments, the [FDA 2005 Food Code Section 3-302.15](#) states that raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form.
- For all food contact equipment and utensils that come into contact with cut melons (such as cutting boards and knives), washing this equipment and the utensils thoroughly with hot soapy water, rinsing, sanitizing, and air-drying before use.
- Using a barrier such as gloves, deli paper, or an appropriate utensil to touch cut melons. Not touching cut melons with bare hands.
- Maintaining the temperature of cut melons at 41°F or below. Displaying cut melons in a refrigerated case, not just displayed on top of ice. Note: Uncut melons do not need to be



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*Draft — Not for Implementation*

refrigerated.

- Marking the date on cut melons that are held more than 24 hours to indicate that they must be consumed or discarded within 7 days.
- Marking the time when cut melons are displayed without refrigeration. Displaying cut melons for a maximum of 4 hours without temperature control and, if not eaten, throwing them away at the end of 4 hours.
- Implementing a pest management program.

Specific procedures for storing or displaying melons, for washing hands, date marking, and for washing and sanitizing equipment can be found in the FDA Food Code.

### **Documentation and Records**

As a general practice, it is important that end-user firms handling melons maintain documentation and records related to operational information about the product and practices, as well as tracing information about the product. It also is important to note that subject to certain exceptions, existing FDA regulations at 21 CFR part 1, subpart J, “Establishment, Maintenance, and Availability of Records,” already impose certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. These records must include identifying information regarding the food. The recommendations below complement, but do not supersede, existing recordkeeping requirements in part 1, subpart J. Note: Restaurants and certain retail food establishments (as those terms are defined in the regulation) are excluded from the recordkeeping requirements of part 1, subpart J.

***Operational records*** about products and practices can be helpful to firms. First, such records help ensure consistency of handling and/or preparation activities and end-product quality and safety. They are more reliable than human memory and serve as a useful tool to identify areas where inconsistencies occur in operations and corrective actions or further employee training may be needed. Furthermore, maintaining adequate documentation and records could assist in identifying or ruling out potential contributing factors of contamination if product implicated in an outbreak is traced to a particular farm or facility.

FDA recommends:

- Developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices and employee training programs.
- Maintaining records for significant activities performed, such as monitoring of storage temperatures; cleaning and sanitation of equipment, containers, and vehicles; employee training; and corrective actions taken.
- Recording information such as the date and time, name of person(s) who completed the record, and the activity being monitored in the documentation.

***Product tracing*** refers to the ability to follow the movement of a food through specified stage(s)



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of production, packing, processing, and distribution. Tracing information about the product facilitates tracking the physical movement of a product from its original source through intermediate sources to its final recipient and tracking product from the final recipient back to its source. Effective product tracing systems can serve as an important complement to food safety programs intended to prevent microbial contamination.

FDA recommends:

- Utilizing information outlined in the GAPs Guide and the FDA Guide to Traceback Investigations to develop a product tracing system applicable to the melon supply chain.
- Developing and maintaining standardized, clear records that can be used to enhance the ability to follow the movement of the product. Examples of such records include records with product identifying information (i.e., labels), invoices, inventory records, bills-of-lading, and shipping/receiving records.

## **X. References**

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday.

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